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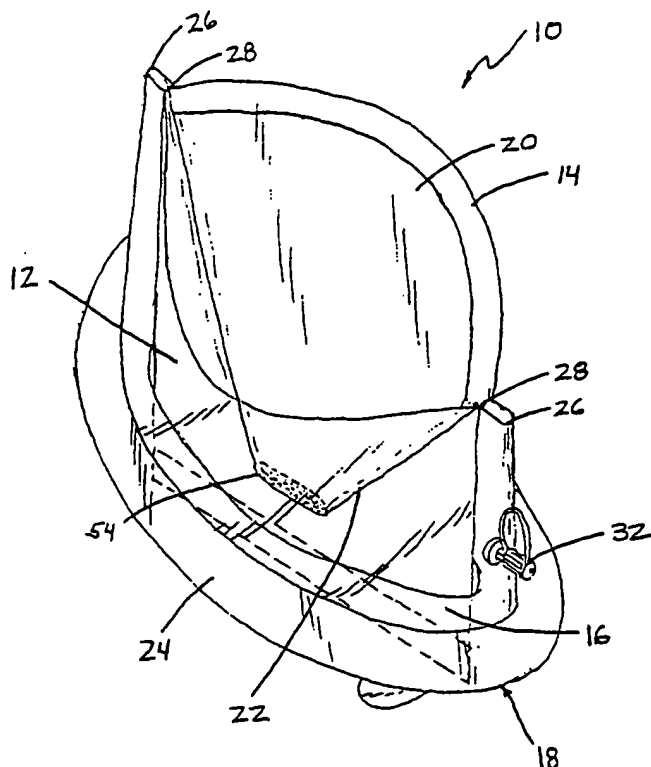
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*For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.*

(54) Title: HAND ACCESS PORT DEVICE



(57) Abstract: An improved access port device (10, 100) is provided which enables hand access to a patient's body cavity while retaining pneumoperitoneum by minimizing gas leakage through the access port device. In one embodiment, the access port device (10) includes first and second sleeves (12, 20) forming an inflatable chamber (30) and a third sleeve (22) mounted within the second sleeve (20) including an elastic band (54) for sealingly engaging a hand or wrist. The access port device (10) may also include an exit opening seal (38) for positioning within the patient's body cavity and a second sleeve retraction prevention device (46) for preventing inadvertent movement of the second sleeve (20) outwardly from the patient's body cavity through the incision. In another embodiment, an access port device (100) is provided which includes an inner annular sealing device (112) and a non-adhesive outer annular sealing device (110) for creating a non-adhesive seal against the outer surface of a patient. An access component (118) forming an inflatable chamber and including an integral sleeved glove (126) may also be provided. In another embodiment, a sealing force applying feature includes a biasing surface (168) formed on a generally flat annular extension (164) and exposed to gas pressure in an adjacent gas chamber (162) positioned to receive leakage gas leaking between the access port device and the patient to create sealing forces which tend to enhance the seal between the flexible annular extension and the patient's skin.

WO 01/08581 A3

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IE 00/00092

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/34 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 22289 A (BONADIO FRANK ; GAYA LTD (IE)) 24 August 1995 (1995-08-24) cited in the application	6,7,9,10
A	page 24, line 24 - line 33; figure 19	1,8,11
X	WO 98 35614 A (MEDICAL CREATIVE TECHNOLOGIES ; DEXTERITY INC (US); CROOK BERWYN M) 20 August 1998 (1998-08-20)	14-16, 43-47, 49-51
Y	page 7, line 10 - line 13	17,18
A	page 8, line 6 - line 10; figure 1	1,17-19, 26,36,62
	— — — — — -/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

26 February 2001

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12.03.01

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/IE 00/00092

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 906 577 A (CARROLL MAUREEN E ET AL) 25 May 1999 (1999-05-25)	36,37, 43-46, 48-50, 52,55-57
A	column 6, line 34 - line 40; figure 2E column 9, line 7 - line 9; figure 5	26,38, 40,53, 54,62
Y	WO 97 11642 A (GEN SURGICAL INNOVATIONS INC) 3 April 1997 (1997-04-03) page 27, line 1 - line 6; figure 28	17,18
A	US 5 636 645 A (OU HONZEN) 10 June 1997 (1997-06-10) column 7, line 23 - line 31; figure 6	1
A	US 5 813 409 A (LEAHY PATRICK F ET AL) 29 September 1998 (1998-09-29) abstract; figure 5	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IE 00/00092

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 42
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 42

Present claim 42 relates to an extremely large number of possible apparatus. In fact, the claims contain so many options that a lack of clarity within the meaning of Article 6.2 a PCT arises to such an extent as to render a meaningful search of the claims impossible.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-5

Access port device with first and second sleeve, securing device and third sleeve including annular elastic band.

2. Claims: 6-13

Access port device with first and second sleeve, securing device and second sleeve retraction prevention device

3. Claims: 14-42

Access port device with sleeve, annular inner and outer sealing device

4. Claims: 43-62

Access port device with sleeve, mounting means, sealing means and retractor for sleeve contact limitation

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IE 00/00092

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9522289 A	24-08-1995	IE 940150 A	04-10-1995
		IE 940613 A	04-10-1995
		IE 950055 A	07-08-1996
		AT 164303 T	15-04-1998
		AU 695770 B	20-08-1998
		AU 1717395 A	04-09-1995
		BR 9506817 A	09-09-1997
		CA 2183064 A	24-08-1995
		CN 1144471 A	05-03-1997
		CZ 9602404 A	16-04-1997
		DE 69501880 D	30-04-1998
		DE 69501880 T	23-07-1998
		EP 0744922 A	04-12-1996
		EP 0807416 A	19-11-1997
		ES 2115365 T	16-06-1998
		FI 963226 A	17-10-1996
		HU 76016 A,B	30-06-1997
		JP 9509079 T	16-09-1997
		NO 963421 A	14-10-1996
		NZ 279907 A	26-06-1998
		PL 315939 A	09-12-1996
		RU 2137453 C	20-09-1999
		US 5803921 A	08-09-1998
		ZA 9501378 A	24-10-1995
WO 9835614 A	20-08-1998	US 5853395 A	29-12-1998
		EP 0996367 A	03-05-2000
US 5906577 A	25-05-1999	AU 7274698 A	24-11-1998
		EP 0981302 A	01-03-2000
		JP 2000501978 T	22-02-2000
		WO 9848724 A	05-11-1998
		US 6142936 A	07-11-2000
WO 9711642 A	03-04-1997	US 5672168 A	30-09-1997
		EP 1000583 A	17-05-2000
		EP 0845960 A	10-06-1998
		US 5957913 A	28-09-1999
US 5636645 A	10-06-1997	NONE	
US 5813409 A	29-09-1998	AU 2240395 A	30-10-1995
		WO 9527468 A	19-10-1995

Irish Short Term Patent
Application No. S990660

"Claims & Abstract"

filed July 28th 2000

In the name of

GAYA LIMITED

CLAIMS:

1. A surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an incision, the device being formed to
5 define a sleeve access port for insertion into the incision and having: -
- mounting means for locating and securing the device in position on a patient;
- sealing means to prevent substantial leakage of gas from the body cavity; and
10 a retractor to limit contact between the sleeve and the incision when in use.
2. A surgical device as claimed in claim 1 optionally wherein: -
- 15 the retractor is provided as a deformable tube, the tube optionally having at opposing ends a proximal ring and a distal ring, the rings being optionally formed for substantially airtight engagement with the sleeve and with the patients abdomen, the ring optionally incorporating an adhesive portion for fixing the ring in position, the distal ring is optionally formed for substantially airtight engagement with the sleeve
20 and with the patients internal abdominal wall;
- engagement between a proximal ring and the sleeve is provided by a skirt carried on the sleeve and having a rim formed for releasable engagement to the ring, the ring and skirt optionally being integrally formed, the skirt optionally having an integrally
25 formed glove for receiving a surgeons hand and or optionally having an integrally formed pocket for receiving a surgical instrument, the skirt may also optionally have a recessed receiver formed for engagement with a ring or a surgeons glove; and

a proximal ring incorporating a flexible gas retaining ring extending down from the proximal ring and formed for engagement against a patients skin when in position to define a gas retention chamber, the gas retaining ring is optionally inflatably movable between an insertion position and an in use position., and the gas retaining ring being optionally provided by a collapsible bellows ring.

3. A surgical device as claimed in claim any of preceding claim wherein the device incorporates a retractor-positioning device, the retractor-positioning device optionally having means for releaseably engaging the proximal ring and the distal ring and optionally in which the means for engaging the proximal ring and the distal ring are movable between a retracted position and a locating position, the means for engaging the proximal ring and the distal ring are optionally telescopically movable, the device further optionally incorporating a collapsible support scaffold, the scaffold being formed for supporting the device in an operative state and collapsible to provide a surgeon free access to the incision.

4. An access port device for use in surgery, comprising:
- a first sleeve of flexible material including a proximal end and a distal end;
 - a securing device attached to said distal end of said first sleeve to secure the access port device externally to a patient;
 - a second sleeve of flexible material attached to the proximal end of said first sleeve, said second sleeve including an entry opening adjacent said proximal end of said first sleeve and an exit opening positioned a spaced distance from said entry opening;
 - an inflatable chamber formed between said first and said second sleeves; and

a third sleeve of flexible material attached to at least one of said first sleeve and said second sleeve, said third sleeve including an annular elastic band positioned between said entry and said exit openings of said second sleeve to sealingly engage a surgeon's arm extending through said third sleeve.

5

5. A surgical device or access port substantially substantially as herein described with reference to and as shown in the accompanying drawings.

10

MACLACHLAN & DONALDSON,
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DUBLIN 2.

HAND ACCESS PORT DEVICEABSTRACT

5 An improved access port device (10,100) is provided which enables hand access to a patient's body cavity while retaining pneumoperitoneum by minimizing gas leakage through the access port device. In one embodiment, the access port device (10) includes first and second sleeves (12,20) forming an inflatable chamber (30) and a third sleeve (22) mounted within the second sleeve (20) including an elastic band (54) for sealingly engaging a hand or wrist.

10 The access port device (10) may also include an exit opening seal (38) for positioning within the patient's body cavity and a second sleeve retraction prevention device (46) for preventing inadvertent movement of the second sleeve (20) outwardly from the patient's body cavity through the incision. In another embodiment, an access port device (100) is provided which includes an inner annular sealing device (112) and a non-adhesive outer annular sealing

15 device (110) for creating a non-adhesive seal against the outer surface of a patient. An access component (118) forming an inflatable chamber and including an integral sleeved glove (126) may also be provided. In another embodiment, a sealing force applying feature includes a biasing surface (168) formed on a generally flat annular extension (164) and exposed to gas pressure in an adjacent gas chamber (162) positioned to receive leakage gas

20 leaking between the access port device and the patient to create sealing forces which tend to enhance the seal between the flexible annular extension and the patient's skin.

[Fig. 1]